

# Vaccine Safety Working Group Update

National Vaccine Advisory Committee  
February 16<sup>th</sup>, 2011

Dr. Marie McCormick  
Co-Chair, Vaccine Safety Working Group

# Members

- Robert Ball (FDA)
- Norman Baylor (FDA)
- Jessica Bernstein (NIH)
- Robert L. Beck
- Guthrie S. Birkhead\*
- Tawny Buck^
- Chris Carlson
- Vito Caserta (HRSA)
- Vicky Debold
- Cornelia Dekker
- Geoffrey Evans (HRSA)
- Mark Feinberg
- Steve Goodman
- Lance Gordon
- Lawrence Gostin (as needed)
- Rita Helfand (CDC)
- Sean Hennessy
- Clement Lewin
- James O. Mason
- Marie McCormick^
- Gerald Medoff
- Karen Midthun (FDA)
- Barbara Mulach (NIH)
- Andrew Pavia^
- William Raub
- L.J. Tan
- Melinda Wharton (CDC)
- Cindy Weinbaum (CDC)

\*Chair of NVAC

^Co-Chair of Vaccine Safety Working Group

# Charge 2

“To review the current federal vaccine safety system and develop a White Paper describing the infrastructure needs for a federal vaccine safety system to fully characterize the safety profile of vaccines in a timely manner, reduce adverse events whenever possible, and maintain and improve public confidence in vaccine safety.”

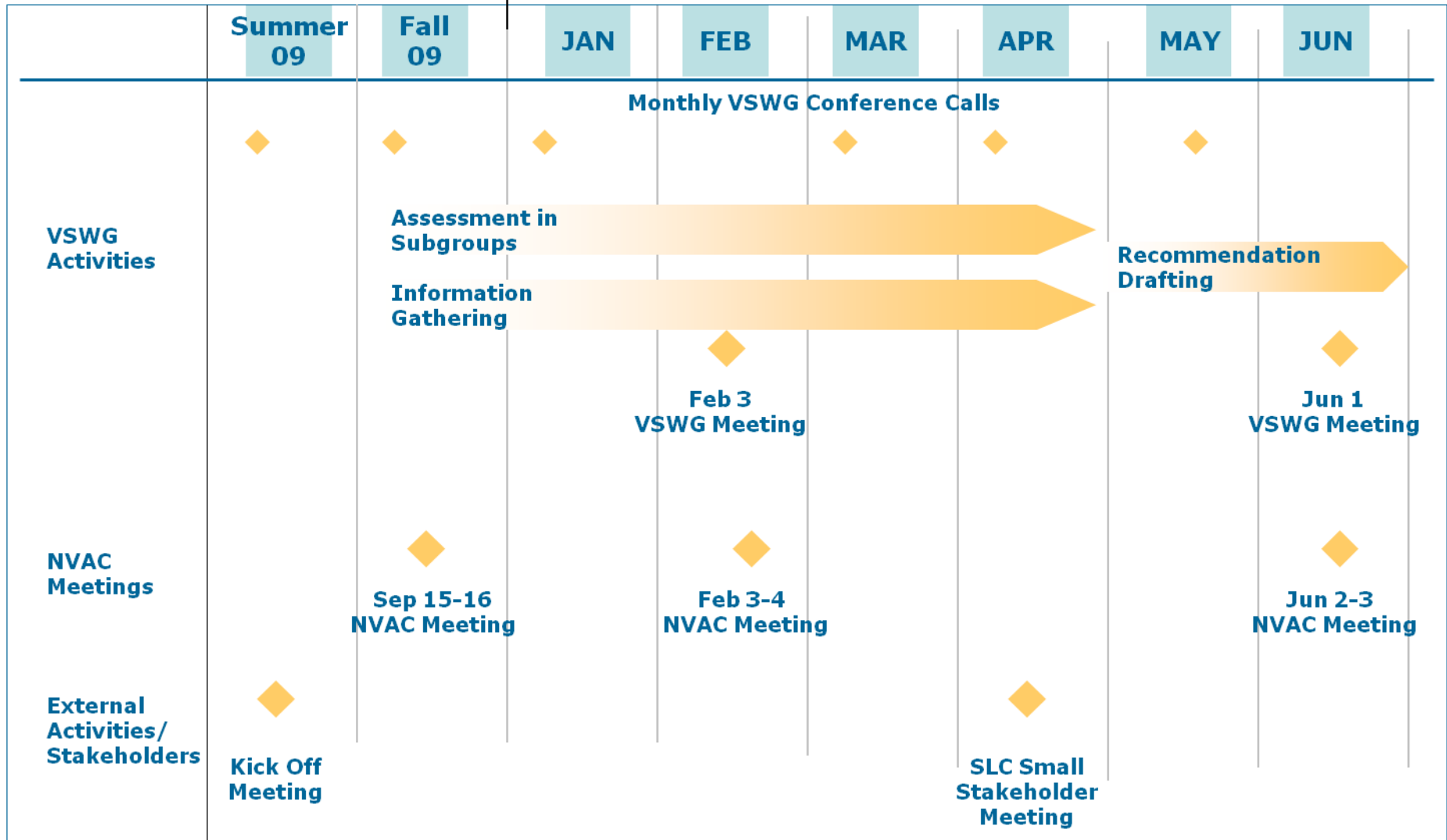
# Working Group Process

- Monthly (+) working group conference calls
- Additional sub-group conference calls
- Correspondence via phone/email
- 3 in person meetings
- Proposed stakeholder engagement meeting
- Public comment solicitation

# NVAC Vaccine Safety Working Group

2010

## Work to Date



# Information Gathering Charge 2 Kick-Off Meeting

- July 15-16, 2009
- Invited 26 panelists to speak on:
  - Principles and policy alternatives for a robust vaccine safety system
  - Identifying innovative ways of overcoming gaps in vaccine safety science infrastructure
  - The ideal system to meet the needs of the public, public health, and healthcare professionals for confidence in vaccine safety
  - Lessons from other safety arenas
  - Enhancing the adoption and implementation of the NVAC white paper

# VSWG Subgroups

## Content Subgroups

1. Structure/Governance (Bill Raub)
2. Epidemiology/Surveillance of Adverse Events (Lance Gordon)
3. Biological Mechanisms of Adverse Events (LJ Tan)

## Process Subgroups

1. Stakeholder Engagement
2. Implementation

# Briefings

- ASTHO Public Confidence study
- Barcoding technology
- CDC Immunization Safety Office
- CISA Biospecimen Repository
- CISA Investigators
- DoD Vaccine Healthcare Centers
- DoD Milvax Drug safety systems
- FDA/CBER
- International vaccine safety systems
- Manufacturers (VSWG members)
- NIH/NIAID
- Past IOM vaccine safety review committee consideration of biological mechanisms
- Post-Licensure Immunization Safety Monitoring (PRISM)
- VSD Investigators
- VA

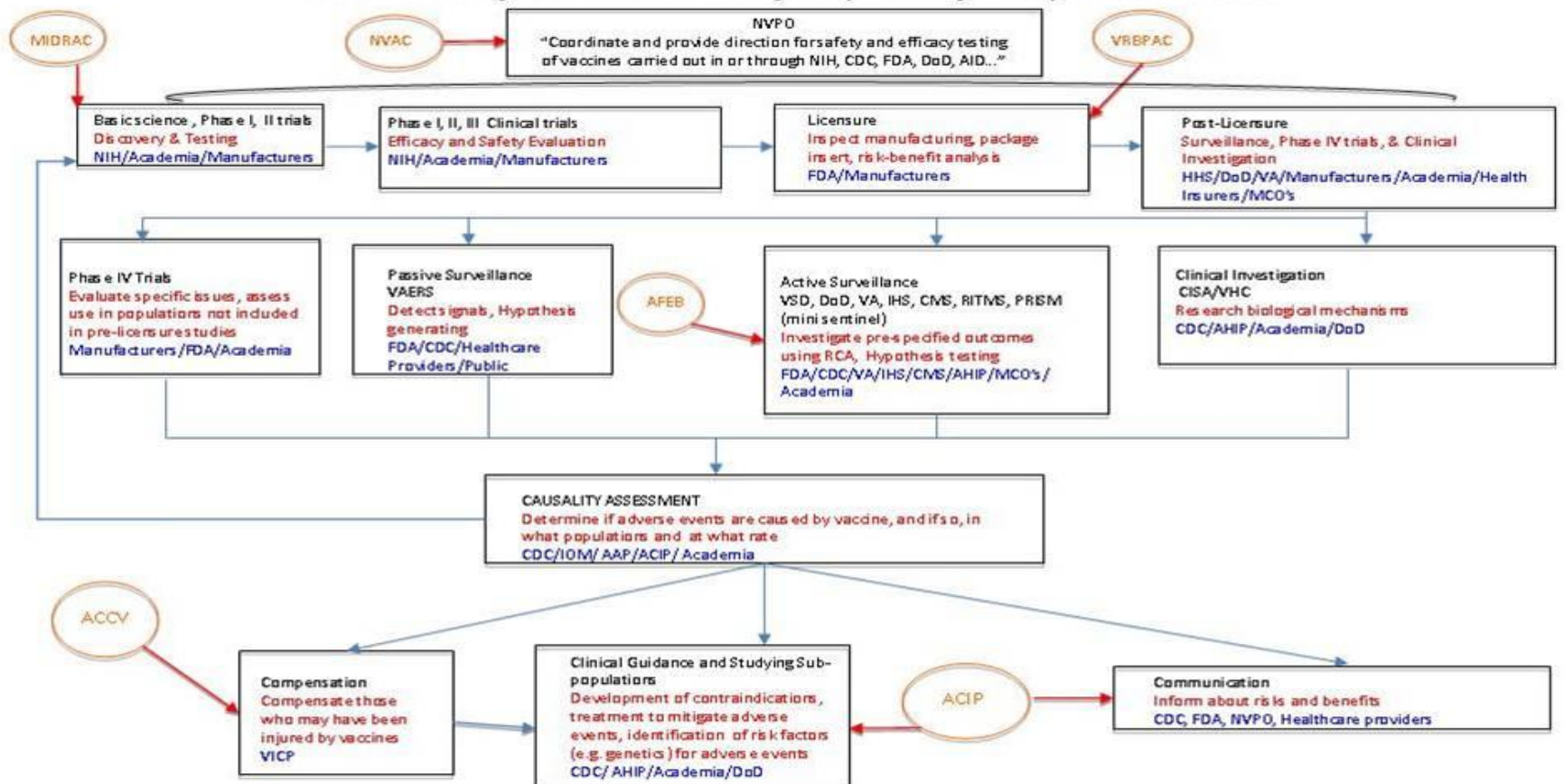


# Information Gathering Salt Lake City Meeting

- April, 2010
- 29 federal and non-federal stakeholders, including 9 VSWG members
- Issues discussed:
  - Opportunities for improvement in the current vaccine safety system
  - Proposed evaluation criteria
  - Strengths and weaknesses of various enhancements or alterations to the structure and governance of the vaccine safety system

# Complexity of the System

## Vaccine Safety Activities & Primary Purposes by Group with Lead Role



### LEGEND



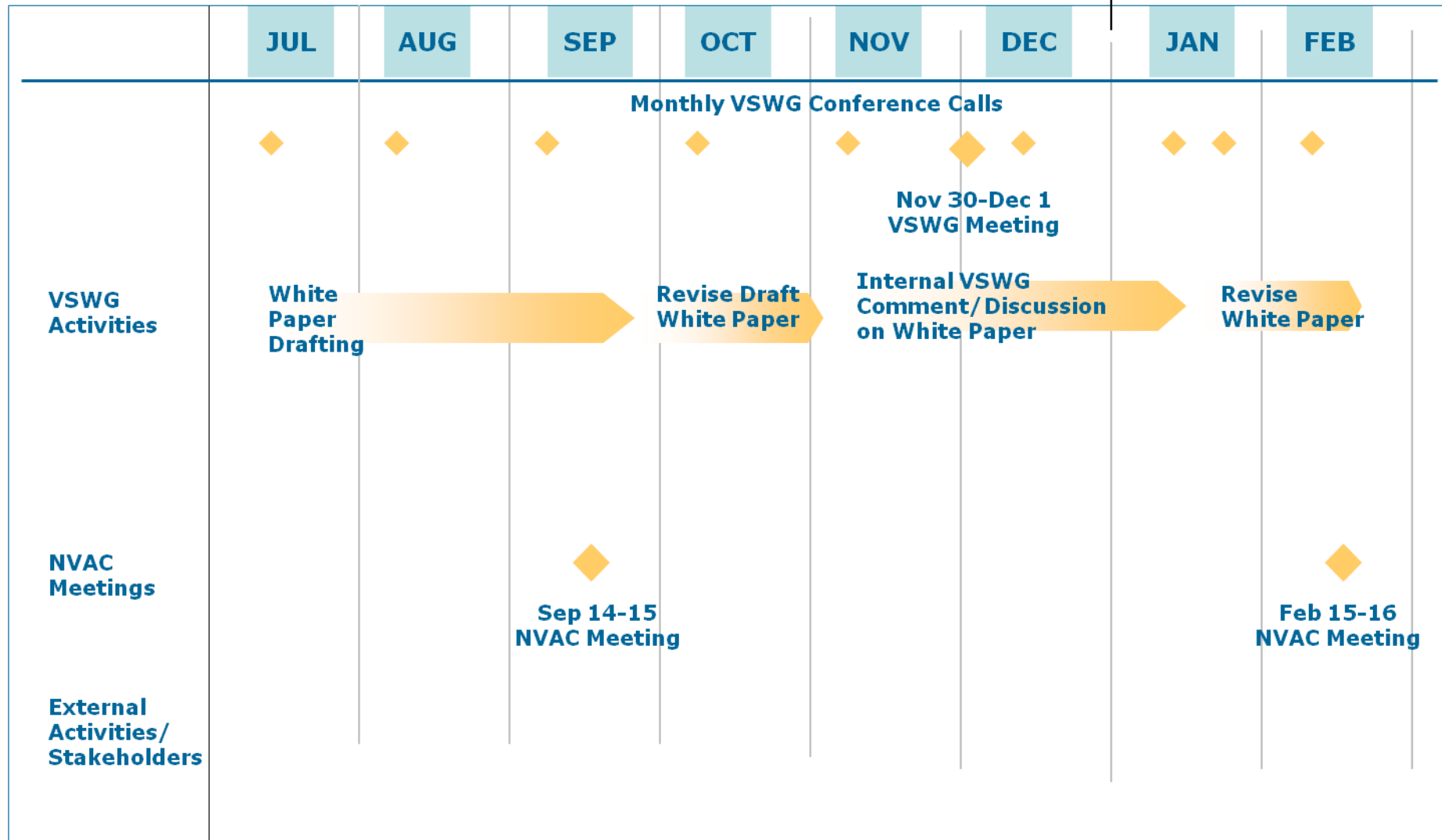
### Acronyms

ACCV = Advisory Committee on Compensation for Vaccine Injury  
 ACIP = Advisory Committee on Immunization Practice  
 AFEB = Armed Forces Epidemiology Board  
 AHIP = America's Health Insurance Plans  
 CDC = Centers for Disease Control and Prevention  
 CISA = Clinical Immunization Safety Assessment network  
 CMS = Centers for Medicare and Medicaid Services  
 DoD = Department of Defense  
 FDA = Food and Drug Administration

IHS = Indian Health Service  
 MIDRAC = Microbiology and Infectious Diseases Review Advisory Committee  
 NIH = National Institutes of Health  
 NVAC = National Vaccine Advisory Committee  
 NVPO = National Vaccine Program Office  
 VA = Veterans' Affairs  
 VAERS = Vaccine Adverse Events Reporting System  
 VICP = Vaccine Injury Compensation Program  
 VSD = Vaccine Safety Datalink

# NVAC Vaccine Safety Working Group

## Work to Date (continued) 2011



# Working Draft sections

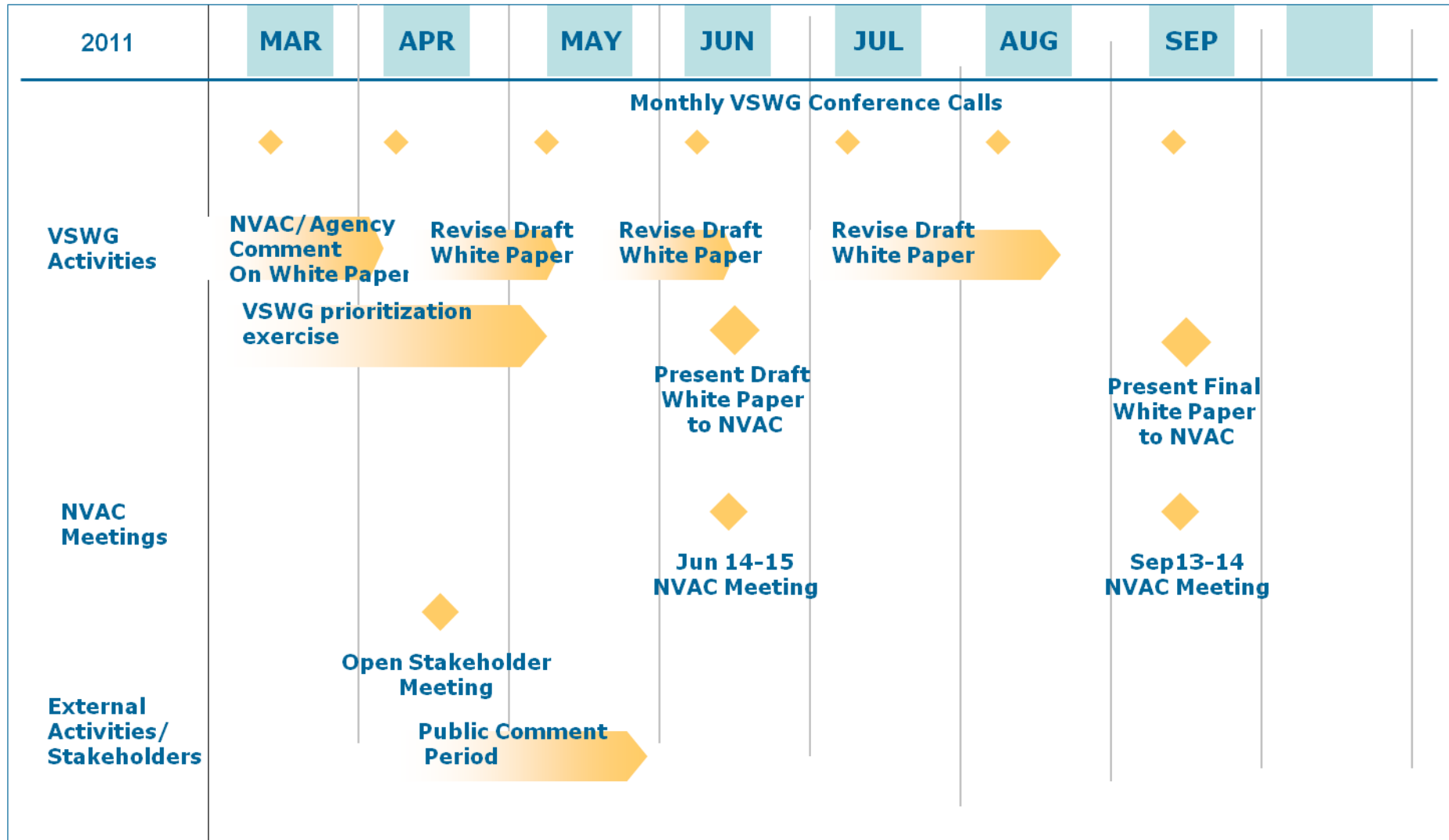
- Introduction
  - Current coverage levels
  - Successes in the current vaccine safety system
  - Opportunities in the current vaccine safety system
- Organization and Methods of the VSWG
- Findings and Results
  - Background
  - Prior recommendations
  - Review of the current vaccine safety system
  - Stakeholder and public input
- Discussion/Conclusions
- Goals of an ideal vaccine safety system
- Recommendations of the VSWG

# Draft Report – 2011 process points

- Current - V0.9 of the draft report is being reviewed, discussed and revised within the working group
- Late February - Full draft report v1.0 to be distributed to NVAC members and Federal Agencies
- Late March – Comments on v1.0 received from NVAC/Agencies
- Mid April – draft v2.0 open for public comment via Federal Register Notice
- April 18 (tentative) Open stakeholder meeting for input on draft v2.0
- Mid May – Public Comment session on v2.0 closes
- Early June - v3.0 distributed for discussion at June NVAC meeting
- September – NVAC vote on VSWG Charge 2 White Paper

# NVAC Vaccine Safety Working Group

## Draft Timeline



# Next Steps

- Feedback from the NVAC and Federal Agencies
- Gather stakeholder and public input
- Recommendation evaluation process
- Revise report for June 2011 NVAC discussion and September 2011 vote.